

REMARKS

Claims 1, 3, 4, 6, 7 and 9-52 are pending in this patent application with claims 1, 4, 7, 10, 14, 17, 21, 25, 29, 32, 37, 43, and 46 being the independent claims.

Based on the following remarks, Applicant respectfully requests that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Rejections Under 35 U.S.C. 103(a)

Claims 1, 3, 4, 6, 7, 9-15, 17-35, and 37-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over reference JP 200312708 to Doi ("Doi") in view of U.S. Patent No. 6,030,554 to Ichihara ("Ichihara"). The Examiner restates that "Doi is silent with respect to a separate container for the articles, which container holds the articles and wherein the two regulators are disposed external to the container." The Examiner combines Doi with Ichihara relying on Ichihara for a teaching that sterilization of an article within its final packaging is known in the field of electron beam sterilization.

Previously, Applicants submitted argument that the Examiner has not provided a source of any teaching or suggestion of a radiation absorbing fixture removably coupled to the external surface of a closed container. The Examiner found that argument unpersuasive and, in response, states that "[t]he Examiner is not required to provide a single reference which teaches each and every claim limitation" for an obviousness rejection to be proper. The Examiner also cited *In re Keller* for the proposition that it is not necessary that structures of two references be physically combinable or that the claimed invention be expressly suggested in any one or all of the cited references, but rather the combined teachings must be considered.

Applicant wholeheartedly agrees with the Examiner that the Examiner need not find a single reference that teaches each and every claim limitation for an obviousness rejection and

never made such an assertion. Further, it appears that the Examiner is relying on *Keller* to support an assertion that the Examiner need not find each recited limitation in at least one of the plurality of cited references. *Keller* does not support such an argument. *Keller* addresses an entirely different requirement of the prima facie case of obviousness.

Each recited feature has to be found somewhere in the cited references, otherwise the Examiner would have to be using impermissible hindsight to form the rejection. That requirement is clearly set forth in MPEP § 2142, which states “the prior art reference (or references when combined) must teach or suggest all the claim limitations.”

The requirement that each limitation is found somewhere in the cited references is separate and distinct from the requirement that “there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings.” That second requirement is also clearly set forth in MPEP § 2142 and was the subject of contention in *Keller*.

In *Keller*, the Applicant appealed an obviousness rejection of claims to a cardiac pacer having a digital counter. *In re Keller*, 208 U.S.P.Q. 871, 880 (C.C.P.A. 1981). In particular, during reissue examination, the examiner rejected the claims over a first reference, the Keller reference, in combination with a second reference, the Walsh reference. *Id.* at 873. The Keller reference was found to disclose the limitations recited in the rejected claims except a digital counter. *Id.* at 880. The Walsh reference, however, disclosed a digital counter, but the combination was argued against because of a lack of motivation to combine the references. *Id.* at 877. Therefore, each limitation recited in the rejected claims was found in at least one of the cited references in *Keller*. As a result, *Keller* is inapplicable to the present argument because in the present case, unlike in *Keller*, at least one limitation recited in each of the independent claims is not disclosed in any of the cited references.

In this instance, neither Doi nor Ichihara discloses a radiation absorbing fixture removeably coupled to an external surface of a closed container. With respect to Doi, the Examiner asserts that the lower half of item 10 in Figure 6A is a container, but the lower half alone is not a closed container. The Examiner further asserts that the upper half of item 10 is considered a regulator. However, if the upper half of item 10 were considered a regulator, it is never removably coupled to an external surface of a closed container.

The Examiner relies upon Ichihara for an assertion that the sterilization of an article within its final packaging is known. Even assuming that the assertion were true, it is not sufficient to overcome the deficiency of Doi. Doi makes no mention of removeably coupling a radiation absorbing fixture to an external surface of a closed container. Ichihara also fails to disclose such a feature. In fact, Ichihara does not even disclose a radiation absorbing fixture.

At best, when viewed as a whole, the combined references could possibly suggest that the combined halves of item 10 in Figure 6A of Doi could be used as final packaging. However, that would simultaneously suggest that a radiation absorbing fixture be built into a closed container, not removably coupled to an external surface of a closed container. Therefore, the combination does not suggest the Applicant's invention.

Each of independent claims 1, 4, 7, 10, 14, 17, 21, 25, 29, 32, 37, 43 and 46, recites a radiation absorbing fixture coupled externally to a closed container. That feature is neither taught nor suggested by Doi or Ichihara, either alone or in combination. As a result, each of those claims is patentable over Doi in view of Ichihara. Claims 3, 6, 9, 11-13, 15, 18-20, 22-24, 26-28, 30, 31, 33-35, 38-42, 44, 45 and 47-52 depend from those independent claims and include all of the features recited in the claim from which each depends. For at least the same reasons, those dependent claims are also patentable over Doi in view of Ichihara.


The Examiner also reasserted the rejection of claims 16 and 36 under 35 U.S.C. § 103(a) as being unpatentable over Doi in view of Ichihara and further in view of U.S. Patent No. 5,590,602 to Peck *et al.* ("Peck"). Claim 16 depends from and includes all of the features recited in claim 14. Claim 36 depends from and includes all of the features recited in claim 32.

As described above, Doi and Ichihara fail to disclose a radiation absorbing fixture removably coupled to an external surface of a closed container. Peck also fails to disclose a radiation absorbing fixture removably coupled to an external surface of a closed container. Therefore, claims 16 and 36 are patentable over Doi in view of Ichihara and Peck.

Conclusion

It is believed this amendment now has placed the application in condition for consideration and allowance. If necessary, the Commissioner is hereby authorized in this and concurrent replies to charge payment (or credit any overpayment) to Deposit Account No. 50-0683 of Luce, Forward, Hamilton & Scripps.

Respectfully submitted,



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